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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,926	09/29/2003	Gregory L. Sundberg	387486	7372

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FAEGRE & BENSON LLP  
PATENT DOCKETING - INTELLECTUAL PROPERTY (32469)  
2200 WELLS FARGO CENTER  
90 SOUTH SEVENTH STREET  
MINNEAPOLIS, MN 55402-3901

EXAMINER
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EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

NOTIFICATION DATE	DELIVERY MODE
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09/30/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/673,926	<b>Applicant(s)</b> SUNDBERG, GREGORY L.	
	<b>Examiner</b> GEORGE EVANISKO	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6,8-11,14-21 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 6, 8-11, 14-21, and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5, 6, 8-11, 14-21, and 24-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the original specification is the fixation helix mechanically supported by and “fixedly” coupled to the piston, in combination with the other elements in the claim(s). The original specification did not describe the fixation helix “fixedly” coupled to the piston and only described the fixation helix “mechanically coupled” with the piston. The metes and bounds of “fixedly” coupled are not set forth in the original disclosure.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5, 6, 8-11, 19-21 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peers-Travarton in view of Bisping (4282885).

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Peers-Travarton shows housing, 12, piston, 40, helix coupled to piston (e.g. figure 2, helix 30 coupled on recess portion), with a housing portion including a helical segmented guide, 32, that rides along the drive mechanism/helical drive grooves (e.g. figure 2, col. 4, lines 10-15), and includes a sleeve of radiopaque material coupled to the housing through the lead. In addition, Peers-Travarton shows the recess in figure 2 as the area right below/above numerals 52 and 46 that is recessed from the large piston, 40, with the helix above the outer surface of the piston. Peers-Travarton's recess does extend inward from the outer surface (as does any recess) of the large piston outer surface, 40. Peers-Travarton discusses the use of rotating the piston 40, to rotate helix, 30, which necessarily would require the helix fixedly coupled to the piston.

See below for the rest of the rejection.

Claims 1, 3, 5, 6, 8-11, 14-21 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vachon in view of Bisping (4282885).

See, for example, figures 4-9 and corresponding description of Vachon that show the piston, helix "fixedly" coupled to the piston by laser welding (e.g. col. 5, line 3), and guide riding in the drive grooves of the helix/first portion of the helix. In addition, figures 4-9 show the recess in the helix as being the indented part of the piston that has a smaller diameter than the largest diameter of the piston. For example, in figure 4, the piston is element 90 (and other parts of piston such as 162, 88, etc), with recess immediately to the left of element 90, where helix 82 is in the recess and above the outer surface of the piston. Vachon's recess does extend inward from the outer surface (as does any recess) of the large piston outer surface, 90

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Peers-Travarton or Vachon discloses the claimed invention except for disclosing part of the fixation helix in a helical recess of a piston, separated by non-recessed portions. Bisping teaches that it is known to use a helical recess on the piston for the helix, separated by non-recessed portions to provide stability to the helix during implantation and extraction. Bisping also teaches that it is known to put nearly the entire part of the fixation helix wire in a helical recess of a piston, separated by non-recessed portions to provide stability to the helix during implantation and extraction (note, the claim is an open ended comprising claim and  $1/3$  to  $1/2$  of the wire is in the recess when the entire helix wire is in the recess). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the medical lead as taught by Peers-Travarton or Vachon, the use of the fixation helix in a helical recess of a piston, separated by non-recessed portions as taught by Bisping since such a modification would provide an implantable lead with part of the fixation helix in a helical recess of a piston, separated by non-recessed portions to provide the predictable results of stability to the helix during implantation and/or extraction.

In the alternative for claims 5, 6 and 21, Peers-Travarton or Vachon in view of Bisping discloses the claimed invention but does not disclose expressly  $1/3$  to  $1/2$  of the diameter of the helix within the piston or the recess having a first width less than a wire diameter. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Peers-Travarton or Vachon in view of Bisping with  $1/3$  to  $1/2$  of the a diameter of the helix within the piston or the recess having a first width less than a wire diameter, because Applicant has not disclosed that  $1/3$  to  $1/2$  of the a diameter of the helix within the piston or the recess having a first width less than a wire diameter provides an advantage, is used for a

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particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the helical fixation within the recess as taught by Peers-Travaton or Vachon in view of Bisping, because it securely holds the wire during implantation.

Therefore, it would have been an obvious matter of design choice to modify Peers-Travaton or Vachon in view of Bisping to obtain the invention as specified in the claim(s).

For claim 18, the Examiner has interpreted the claim similar to the applicant's disclosure as being one recess having multiple portions, which Bisping shows.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peers-Travarton in view of Bisping discussed above. Peers-Travarton in view of Bisping disclose the claimed invention except for the conductor electrically connected to the piston, the piston electrically connected to the helix, and the active helix. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable heart lead as taught by Peers-Travarton in view of Bisping, with the conductor electrically connected to the piston, the piston electrically connected to the helix, and the active helix since it was known in the art that medical leads use a conductor electrically connected to the piston, piston electrically connected to the helix, and active helix to provide the predictable results of a helical fixation lead that actively directly stimulates cardiac tissue at the fixation site and allows for bipolar pacing and sensing.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Vachon as discussed above. In the alternative for the above rejection of claims 8 and 10, the modified Vachon discloses the claimed invention except for the guide being a segmented helical guide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead as taught by the modified Vachon, with the guide being a helical segmented guide since it was known in the art that implantable leads use a guide being a helical segmented guide to provide the predictable result of easily and smoothly advancing the helix from the lead.

#### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GEORGE EVANISKO whose telephone number is (571)272-4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on 571 272 4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/  
Primary Examiner, Art Unit 3762

GRE  
9/25/11